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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,169	08/16/1999	CAROLYN R. AITA	26767-1000	4691

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EXAMINER
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MCNEIL, JENNIFER C

ART UNIT	PAPER NUMBER
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1775

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/375,169

Applicant(s)

AITA ET AL.

Examiner

Jennifer C McNeil

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1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-10,12-16,18,19,21-26,28,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,19 and 21-26 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-10,12-16,28,30,32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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DETAILED ACTION

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 30, ~~31~~, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 28 has been amended to include the phrase "at least in part" in reference to the outer coating. There is no clear support in the specification for an outer layer being formed "at least in part" of one of these compositions. This alludes clearly to the presence of additional materials in the outer layer. Applicant makes no known reference to any material other than those specifically named in the instant specification being in the outer layer. Applicant also refers to the necessity of the outer layer being made of these materials to perform the desired function of forming a hydrate or hydroxide compound upon contact with an oxygen-containing environment. Applicant does not appear to establish any basis for additional materials, nor does applicant make any such materials known.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 7-10, and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 1 to specify that the bilayer is made of two

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different materials, but does not clarify whether the bilayer is formed of a first layer of a first ceramic material and a second layer of a second ceramic material different from the first ceramic material.

### *Response to Arguments*

Applicant argues that claim 1 has express language calling for the second ceramic material to be different from the first ceramic material. This language is not used in reference to “layers” of the “bilayer” as reflected in the other independent claims.

Regarding the 112 first paragraph rejection, applicant states that the Examiner has misinterpreted “outer component”. The claim refers to an “outer coating component” “being formed at least in part of a compound selected from the group...”. The specification refers to the outer or third module as:

A third or outer module disposed on the second module comprises a third-module compound capable of forming a hydrate or hydroxide compound upon contact in an oxygen containing environment, such as blood. The third module preferably comprises an aluminum, zirconium or hafnium compound, more preferably, a nitride of these materials. Module III comprises a single, relatively thicker layer of nanocrystalline aluminum nitride and provides

It is not found where the specification enables one of ordinary skill in the art to form the outer coating component or third module with materials other than those taught. Applicant is invited to point out in the specification where there is support for the “outer coating component” being formed of materials other than one of those above. Also, applicant is asked to clearly define what is being considered the “outer coating component”. Is it to be considered the third module?

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*Allowable Subject Matter*

Claims 9 and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 18, 19, and 21-26 are allowed.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer C McNeil whose telephone number is 571-272-1540. The examiner can normally be reached on 9AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer McNeil  
Primary Examiner